

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Donald R. OWEN et al.

Application No.: Rule 53(b) Divisional of
Appln No. 09/645,525

Filed: July 11, 2003

Docket No.: 040219.03

For: APPARATUS AND METHOD FOR MAINTAINING AND/OR RESTORING VIABILITY
OF ORGANS

INFORMATION DISCLOSURE STATEMENT

Director of the U.S. Patent and Trademark Office
Washington, D.C. 20231

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- ☒ 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date or the date of filing a CPA, OR (b) before the mailing date of a first Office Action on the merits in the present application. No certification or fee is required.
- ☒ 2. The references were cited by or submitted to the Office in Application No. 09/645,525, filed August 25, 2000, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 CFR §1.98(d).

Respectfully submitted,



William P. Berridge
Registration No. 30,024

Kevin M. McKinley
Registration No. 43,794

WPB:KMM/jfl

Date: July 11, 2003

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 15-0461
--

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. Owen et al.			
				FILING DATE July 11, 2003		GROUP	

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS
		5,699,793	12/23/97	Brasile		
		5,843,024	12/1/98	Brasile		
		5,702,881	12/30/97	Brasile et al.		
		5,643,712	7/1/97	Brasile		
		3,545,221	12/08/70	Swenson et al.		
		1,682,344	08/28/28	Lesieur		
		1,916,658	07/04/33	Davidson		
		3,406,531	10/22/68	Swenson et al.		
		3,607,646	10/21/71	de Roissart		
		3,632,473	01/04/72	Belzer		
		3,639,084	02/01/72	Goldhaber		

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS
		0 256 653	02/24/88	EUROPE		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)	
	"GLUTATHIONE S-TRANSFERASE PREDICTS OUTCOME OF MACHINE PRESERVED NHBD KIDNEYS", J.H. Loemen and C. Kootstra, Abstract submitted for presentation at XVth International Congress of the Transplantation Society, Aug. 1996.
	"RENAL PRESERVATION AFTER WARM ISCHEMIA USING OXYGEN FREE RADICAL SCAVENGERS TO PREVENT REPERFUSION INJURY", Pedro Baron et al., <u>Journal of Surgical Research</u> , Vol. 51, pgs. 60-65, 1991.
	"ORGAN PRESERVATION", J.H. Southard, Ph.D. and F.O. Belzer, M.D., <u>Principles of Organ Transplantation</u> , Chapter 10, pgs. 194-215, 1989.
	"ORGANKO SERVIERUNGSMACHINE OKM 82", Von Dietmer Scholz et al., East German Article, 1983.
	"ARREST OF CEREBRAL BLOOD FLOW AND REPERFUSION OF THE BRAIN IN THE RHESUS MONKEY", L.R. Wolin, L.C. Massopust, Jr., R.J. White and N. Taslitz, <u>Resuscitation</u> , Vol. 1 39, 1972.
	"NUTRITIONAL ASPECTS OF AMBULATORY CARE-OXYGEN RADICALS AND DISEASE-NO. 1", Hoffmann-La Roche, Vol. 42, No. 3, pgs. 557-558, Sept. 1990.
	"CEREBRAL ISCHEMIC INJURY", Blaine C. White, <u>Emergency Medicine-A Comprehensive Study Guide</u> , Second Edition, pgs. 9-10, 1988.

EXAMINER	DATE CONSIDERED
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. Owen et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		3,660,241	05/02/72	Michielsen			
		3,738,914	06/12/73	Thorne et al.			
		3,753,865	08/21/73	Belzer et al.			
		3,772,153	11/13/73	de Roissart			
		3,777,507	12/11/73	Burton et al.			
		3,810,367	05/14/74	Peterson			
		3,843,455	10/22/74	M. Bier			
		5,681,740	10/1997	Messier et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		0 297 723	01/04/89	EUROPE			
		1-213276	08/28/89	JAPAN			
		38 08 942	09/28/89	GERMANY			
		376 763	07/04/90	EUROPE			
		2-258701	10/19/90	JAPAN			
		WO 01/01774 A1	01/11/01	WIPO			
		GB 1442356 A	07/1976	UNITED KINGDOM			
		WO 00/18226	04/06/00	WIPO			
		WO 96/30111	10/03/96	WIPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		"CEREBRAL BLOOD FLOW, VASOREACTIVITY, AND OXYGEN CONSUMPTION DURING BARBITURATE THERAPY IN SEVERE TRAUMATIC BRAIN LESIONS" Carl-Henrik Nordstrom et al., <u>J. Neurosurg.</u> , Vol. 68, pgs. 424-431, March 1988.					
		"AT SURGERY'S FRONTIER: SUSPENDED ANIMATION", <u>New York Times</u> , C1, C2, Nov. 13, 1990.					
		"RANDOMIZED CLINICAL STUDY OF THIOPENTAL LOADING IN COMATOSE SURVIVORS OF CARDIAC ARREST", <u>The New England Journal of Medicine</u> , Vol. 314, No. 7, pgs. 397-403, Feb. 1996.					
		"CURRENT CONCEPTS IN BRAIN RESUSCITATION", Mark C. Rodgers et al., <u>J. American Medical Assn.</u> , Vol. 261, No. 21, pgs. 3143-3147, June 1989.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. Owen et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		3,881,990	05/06/75	Burton et al.			
		3,892,628	07/01/75	Thorne et al.			
		3,914,954	10/28/75	Doerig			
		4,186,565	2/5/80	Toledo-Pereyra			
		4,231,354	11/4/80	Kurtz et al.			
		60/459,986	04/04/03	David W. WRIGHT et al.			
		60/459,981	04/04/03	David W. WRIGHT et al.			
		60/460,875	04/08/03	David W. WRIGHT et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		163 242 8	07/03/91	SOVIET UNION			
		93/00808	01/21/93	PCT			
		94/06292	03/31/94	PCT			
		96/05727	02/29/96	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		"CEREBROVASCULAR HYPOXIC AND AUTOREGULATORY RESPONSES DURING REDUCED BRAIN METABOLISM", Judith H. Donegan et al., <u>Am. J. Physiol.</u> , Vol. 249, pgs. H421-429, 1985.					
		"REGIONAL CEREBRAL BLOOD FLOW IN NORMAL BLOOD CIRCULATED AND PERFLUOROCARBON TRANSFUSED RATS", P.A. Lee et al., <u>Adv. Exp. Med. Biol.</u> , Vol. 200, pgs. 59-65, 1986.					
		"PROTECTION FROM CEREBRAL AIR EMBOLI WITH PERFLUOROCARBONS IN RABBITS", Bruce D. Spiess, M.D. et al., <u>Stroke</u> , Vol. 17, No. 6, pgs. 1146-1149, 1986.					
		"FREE RADICALS AND MYOCARDIAL ISCHEMIA AND REPERFUSION INJURY", Paul J. Simpson et al., <u>J Lab Cin Med.</u> , pgs. 13-30, July 1987.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. Owen et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		3,962,439	06/08/76	Yokoyama et al.			
		3,995,444	12/07/76	Clark et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		96/32074	10/17/96	PCT			
		96/32157	10/17/96	PCT			
		2 226 482	01/04/73	GERMANY			
		760972	09/07/80	SOVIET UNION			
		0 096 997	12/28/83	EUROPE			
		221 361	04/24/85	GERMANY			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		"INCREASES IN BRAIN TUMOR AND CEREBRAL BLOOD FLOW BY BLOOD-PERFLUOROCHEMICAL EMULSION (FLUOSOL-DA) EXCHANGE", Shoji Hiraga et al., <u>Cancer Research</u> , Vol. 47, pgs. 3296-3302, June 15, 1987.					
		"POLAROGRAPHIC CEREBRAL OXYGEN AVAILABILITY, FLUORCARBON BLOOD LEVELS AND EFFICACY OF OXYGEN TRANSPORT BY EMULSIONS", Leland C. Clark Jr. et al., <u>Biomaterials</u> , Vol. 16(1-3), pgs. 375-393, 1988.					
		"EASIER BREATHING IN RDS", J.C., <u>Medical Tribune</u> , Jan. 11, 1990.					
		"90'S COULD SEE BRAIN INJURY REVERSAL", Rebecca Voelker, <u>American Medical News</u> , Nov. 17, 1989.					
		"COOLING BRAIN MAY LIMIT STROKE DAMAGE", <u>American Medical News</u> , p. 66, Nov. 17, 1989.					
		"DRUG MAY PRESERVE HEART TISSUE AFTER ATTACK", <u>The New York Times Company</u> , p. 3, Sept. 5, 1989.					
		"RADICAL THERAPY", <u>Scientific American</u> , Sept. 1987.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)	US Dept. of Commerce PATENT & TRADEMARK OFFICE	ATTY DOCKET NO. 040219.03	APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANT(S) Donald R. Owen et al.	
		FILING DATE July 11, 2003	GROUP

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS
		4,242,883	01/06/81	Toledo-Pereyra		
		4,243,883	06/06/81	Schwarzmann		
		4,378,797	04/05/83	Osterholm		
		4,393,863	07/19/83	Osterholm		
		4,445,500	05/01/84	Osterholm		
		4,451,251	05/29/84	Osterholm		
		4,462,215	07/31/84	Kuraoka et al.		

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)	
	"RESUSCITATION OF THE RABBIT BRAIN AFTER ACUTE COMPLETE ISCHEMIA LASTING UP TO ONE HOUR: PATHOPHYSIOLOGICAL AND PATHOMORPHOLOGICAL OBSERVATIONS", Ryszard Pluta, <u>Resuscitation</u> , Vol. 15, pgs. 267-287, 1987.
	"DISEASES OF THE NERVOUS SYSTEM", Arthur K. Asbury et al., Vol. 2, pgs. 1071 and 1083, 1986.
	"IN SITU CADAVER KIDNEY PERFUSION", Robert T. Schweizer et al., <u>Transplantation</u> , Vol. 32, No. 6, pgs. 482-484, Dec. 1981.
	"USE OF EXTRACORPOREAL CADAVER PERFUSION FOR PREPARATION OF ORGAN HOMOGRAFTS", T.L. Marchioro et al., <u>Surgical Forum</u> , Vol. XIV, pgs. 174-176, 1963.
	"PRESERVATION OF CEREBRAL FUNCTION DURING CIRCULATORY ARREST AND RESUSCITATION: HYPOTHERMIC PROTECTIVE CONSIDERATIONS", Robert J. White, <u>Resuscitation</u> , Vol. I, pgs. 107-115, 1972.
	"IN SITU KIDNEY PRESERVATION FOR TRANSPLANTATION WITH USE OF PROFOUND HYPOTHERMIA (5 TO 20° C.) WITH AN INTACT CIRCULATION", A. R. Moossa et al., <u>Society For Vascular Surgery</u> , Vol. 79, No. I, pgs. 60-64, Jan. 1976.
	"ANNALS OF CLINICAL AND LABORATORY SCIENCE", F. William Sunderman, M.D., Ph.D., <u>Official Journal of the Association of Clinical Scientists</u> , Vol. 20, No. 4, page 292, July-Aug. 1990
	"EXTRACORPOREAL PERFUSION FOR OBTAINING POSTMORTEN HOMOGRAFTS", T.L. Marchioro et al., <u>Surgery</u> , Vol. 54, No. 6, pgs. 900-911, July-Dec. 1963.

EXAMINER	DATE CONSIDERED
----------	-----------------

Examiner:	Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
-----------	---

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. Owen et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		4,471,629	09/18/84	Toledo-Pereyra			
		4,474,016	10/02/84	Winchell			
		4,502,295	03/05/85	Toledo-Pereyra			
		4,559,298	12/17/85	Fahy			
		4,494,385	12/22/85	Kuraoka et al.			
		4,596,250	06/24/86	Beisang, III et al.			
		4,618,586	10/21/86	Walker			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		"THE NATURE OF FLUOROCARBON ENHANCED CEREBRAL OXYGEN TRANSPORT", Leland C. Clark et al., <u>Adv. Exp. Med. Biol.</u> , Vol. 248, pgs. 341-355, 1989.					
		"STORAGE AND TRANSPORT OF HEART AND HEART-LUNG DONOR ORGANS WITH INFLATABLE CUSHIONS AND EUTECTOID COOLING", D.R. Wheeldon et al., <u>The Journal of Heart Transplantation</u> , Vol. 7, pgs. 265-268, 1988.					
		"DECREASED NEPHROTOXICITY AFTER THE USE OF MICROEMULSION FORMULATION OF CYCLOSPORINE A COMPARED TO CONVENTIONAL SOLUTION", J. Ahlmén et al., <u>Transplantation Proceedings</u> , Vol. 27, No. 6, pgs. 3432-3433, Dec. 1995.					
		"DEVELOPMENT OF AN ISOLATED PERFUSED DOG KIDNEY WITH IMPROVED FUNCTION", William H. Waugh et al., <u>American Journal of Physiology</u> , Vol. 217, No. 1, July 1969.					
		"LOW COST APPARATUS FOR PRIMER-DIRECTED DNA AMPLIFICATION USING <i>THERMUS AQUATICUS</i> -DNA POLYMERASE", Helge Torgersen et al., <u>Analytical Biochemistry</u> , Vol. 176, pgs. 33-35, 1989.					
		"SIMPLE PROGRAMMABLE APPARATUS FOR ENZYMATIC DNA AMPLIFICATION", Royal A. McGraw et al., <u>DNA and Protein Engineering Techniques</u> , Vol. 1, No. 5, pgs. 65-67, 1988					
		"AN ORGAN CRYOPRESERVATION APPARATUS", Michael G. O'Callaghan et al., <u>IEEE Transactions On Biomedical Engineering</u> , Vol. BME-24, No. 2, pgs. 111-115, March 1997.					
		"TRANSPLANTATION OF RABBIT KIDNEYS PERFUSED WITH GLYCEROL SOLUTIONS AT 10°C", I.A. Jacobsen et al., <u>Cryobiology</u> , Vol. 15, pgs. 18-26, 1978.					
		"DISTRIBUTION OF REMOVAL OF GLYCEROL BY VASCULAR ALBUMIN PERFUSION IN RABBIT KIDNEYS", IB A. Jacobsen, <u>Cryobiology</u> , Vol. 15, pgs. 302-311, 1978.					
		"BANKING OF CELLS, TISSUES, AND ORGANS AT LOW TEMPERATURES", David E. Pegg, <u>Current Trends in Cryobiology</u> , Plenum Press, NY, pgs. 153-180, 1970.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. Owen et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		4,629,686	12/16/86	Gruenberg			
		4,657,532	04/14/87	Osterholm			
		4,666,425	05/19/87	Fleming			
		4,704,029	11/03/87	Van Heuvelen			
		4,723,974	02/09/88	Ammerman			
		4,745,759	05/24/88	Bauer et al.			
		4,766,740	08/30/88	Bradley et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		"ACTIVATION OF ALPHA ADRENERGIC VASOCONSTRICTOR RESPONSE IN KIDNEYS STORED AT -30°C FOR UP TO 8 DAYS", Gregory M. Fahy, <u>Cryo-Letters</u> , Vol. 1, pgs. 312-317, 1980.					
		"HISTOLOGICAL CRYOPROTECTION OF RAT AND RABBIT BRAINS", G.M. Fahy et al., <u>Cryo-Letters</u> , Vol. 5, pgs. 33-46, 1984.					
		"VITRIFICATION AS AN APPROACH TO CRYOPRESERVATION", G.M. Fahy et al., <u>Cryobiology</u> , Vol. 21, pgs. 407-426, 1984.					
		"A FULLY AUTOMATED SYSTEM FOR TREATING ORGANS WITH CRYOPROTECTIVE AGENTS", G.M. Fahy et al., <u>Cryobiology</u> , Vol. 22, pgs. 607-608, 1985.					
		"PERFUSION OF RABBIT KIDNEYS WITH CRYOPROTECTIVE AGENTS", D.E. Pegg, <u>Cryobiology</u> , Vol. 9, pgs. 411-419, 1972.					
		"PERFUSION OF RABBIT KIDNEYS WITH GLYCEROL SOLUTIONS AT 5°C", D.E. Pegg et al., <u>Cryobiology</u> , Vol. 14, pgs. 168-178, 1977.					
		"MOX®-100 RENAL PRESERVATION SYSTEM", Waters Instruments Medical Group, pgs. 2-7, 1982.					
		"ENGINEERING ASPECTS OF EQUIPMENT DESIGN FOR SUBZERO ORGAN PRESERVATION", G.J. Sherwood et al., <u>Organ Preservation</u> , Chapter 15, pgs 152-174, 1973.					
		"ORGAN PERFUSION SYSTEMS: AN EVALUATION CRITERIA", Fereydoon Sadri, Ph.D., <u>T.O.P.S. Medical Corporation</u> , pgs. 1-8, 1987.					
		"SELENO-DL-METHIONINE REDUCES FREEZING INJURY IN HEARTS PROTECTED WITH ETHANEDIOL", W.J. Armitage et al., <u>Cryobiology</u> , Vol. 18, pgs. 370-377, 1981.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. Owen et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		4,801,299	01/31/89	Brendel et al.			
		4,837,390	06/06/89	Reneau			
		4,879,283	11/07/89	Belzer et al.			
		4,951,482	08/28/90	Gilbert			
		4,958,506	09/25/90	Guilhem et al.			
		5,003,787	04/02/91	Zlobinsky			
		5,028,588	07/02/91	Hoffman et al.			
		5,036,097	07/30/91	Floyd et al.			
		5,047,395	09/10/91	Wu			
		5,051,352	09/24/91	Martindale et al.			
		5,066,578	11/19/91	Wikman-Coffelt			
		5,085,630	02/04/92	Osterholm et al.			
		5,110,721	05/05/92	Anaise et al.			
		5,130,230	07/14/92	Segall et al.			
		5,141,847	08/25/92	Sugimachi et al.			
		5,145,771	09/08/92	Lemasters et al.			
		5,149,321	09/22/92	Klatz et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		"ISOLATED PERFUSION OF WHOLE ORGANS", F.O. Belzer et al., <u>Preservation</u> , Chapter 1, pgs. 3-12, 1968.					
		"VARIATIONS IN VASCULAR RESISTANCE OF ISOLATED RAT HEARTS DURING NORMOTHERMIC AND HYPOTHERMIC EXPERIMENTS", C.G. Adem et al., <u>J. Biomed. Engng.</u> , Vol. 3(2), pgs. 128-133, 1981.					
		"COMPUTER CONTROL OF A MODIFIED LANGENDORFF PERFUSION APPARATUS FOR ORGAN PRESERVATION USING CRYOPROTECTIVE AGENTS", C.G. Adem et al., <u>J. Biomed. Engng.</u> , Vol. 3, pgs. 134-139, April 1981.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. Owen et al.			
				FILING DATE July 11, 2003		GROUP	

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS
		5,157,930	10/27/92	McGhee et al.		
		5,200,176	04/06/93	Wong et al.		
		5,216,032	06/01/93	Manning		
		5,217,860	06/08/93	Fahy et al.		
		5,234,405	08/10/93	Klatz et al.		
		5,285,657	02/15/94	Bacchi et al.		
		5,328,821	07/12/94	Fisher et al.		
		5,338,662	08/16/94	Sadri		
		5,356,771	10/18/94	O'Dell		
		5,362,622	11/08/94	O'Dell et al.		
		5,383,854	01/24/95	Safar et al.		
		5,385,821	01/31/95	O'Dell et al.		
		5,395,314	03/07/95	Klatz et al.		
		5,434,045	07/18/95	Jost		
		5,437,633	08/01/95	Manning		
		5,472,876	12/05/95	Fahy		
		5,584,804	12/17/96	Klatz et al.		
		5,586,438	12/24/96	Fahy		
		5,599,659	02/04/97	Brasile et al.		
		5,712,084	01/27/98	Osgood		
FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS

EXAMINER	DATE CONSIDERED
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. OWEN et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		WO 97/28449	08/07/97	PCT			
		WO 96/12191	04/25/96	PCT			
		WO 96/31779	10/10/96	PCT			
		WO 97/22003	06/19/97	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		"EFFECT OF PHARMACOLOGIC AGENTS ON THE FUNCTION OF THE HYPOTHERMICALLY PRESERVED DOG KIDNEY DURING NORMOTHERMIC REPERFUSION", Rutger J. Ploeg et al., <u>Surgery</u> , Vol. 103, No. 6, pgs. 676-682, June 1988.					
		"INTERMEDIATE NORMOTHERMIC PERFUSION DURING COLD STORAGE OF ISCHEMICALLY INJURED KIDNEYS", J.G. Maessen et al., <u>Transplantation Proceedings</u> , Vol. 21, No. 1, pgs. 1252-1253, Feb. 1989.					
		"THE BENEFICIAL EFFECT OF INTERMEDIATE NORMOTHERMIC PERFUSION DURING COLD STORAGE OF ISCHEMICALLY INJURED KIDNEYS", Jos G. Maessen et al., <u>Transplantation</u> , Vol. 47, No. 3, pgs. 409-414, March 1989.					
		"THE ASYSTOLIC, OR NON-HEARTBEATING, DONOR", Gauke Kootstra, <u>Transplantation</u> , Vol. 63, No. 7, pgs. 917-921, 1997.					
		"THE USE OF HEMOGLOBIN SOLUTIONS IN KIDNEY PERFUSIONS", F.H. Daniels et al., <u>CRC Critical Reviews In Biomedical Engineering</u> , Vol. 9, Issue 4, pgs. 315-345, 1984.					
		"NORMOTHERMIC RENAL ARTERY PERFUSION: A COMPARISON OF PERFUSATES", John D. Hughes et al., <u>Annals of Vascular Surgery</u> , Vol. 10, pgs. 123-130, 1996.					
		"IS NORMOTHERMIC PRESERVATION AN ALTERNATIVE TO HYPOTHERMIC PRESERVATION?", R. N. Dunn et al., <u>Organ Preservation Basic and Applied Aspects</u> , Chapter 38, pgs. 273-277, 1982.					
		"MILD HYPOTHERMIA GIVES BETTER FUNCTIONAL PRESERVATION THAN COLD OR NORMOTHERMIC PERFUSION OF RAT KIDNEYS", B.L. Kasiske et al., <u>Transplantation Proceedings</u> , Vol. 22, No. 2, pgs. 472-473, April 1990.					
		"STUDIES OF CONTROLLED REPERFUSION AFTER ISCHEMIA", Pierre L. Julia, MD et al., <u>The Journal of Thoracic and Cardiovascular Surgery</u> , Vol. 101, No. 2, pgs. 303-13, Feb. 1991.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. OWEN et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		"URINARY π -CLASS GLUTATHIONE TRANSFERASE AS AN INDICATOR OF TUBULAR DAMAGE IN THE HUMAN KIDNEY", Dr. Anders Sundberg et al., <u>Nephron</u> , Vol. 67, pgs. 308-316, 1994.					
		"EFFECT OF ISCHEMIA AND 24 HOUR REPERFUSION ON ATP SYNTHESIS IN THE RAT KIDNEY", C.E. Irazu et al., <u>Journal of Experimental Pathology</u> , Vol. 4, No. 1, pgs. 29-36, 1989.					
		"INTERMEDIATE NORMOTHERMIC HEMOPERFUSION OF RAT KIDNEYS: FUNCTIONAL ASPECTS AND A STUDY INTO THE EFFECT OF FREE RADICAL SCAVENGERS", A.O. Gaber, <u>Transplantation Proceedings</u> , Vol. XX, No. 5, pgs. 896-898, Oct. 1998.					
		"IMPROVEMENT OF POSTISCHEMIC KIDNEY FUNCTION BY REPERFUSION WITH A SPECIFICALLY DEVELOPED SOLUTION (BT01)", Pierre Julia, MD et al., <u>Annals of Vascular Surgery</u> , Vol. 9, pgs. s-81-s-88, 1995.					
		"ISCHEMIA WITH INTERMITTENT REPERFUSION REDUCES FUNCTIONAL AND MORPHOLOGIC DAMAGE FOLLOWING RENAL ISCHEMIA IN THE RAT", Richard S. Frank, MD et al., <u>Annals of Vascular Surgery</u> , Vol. 7, No. 2, pgs. 150-155, 1993.					
		"GRAFT CONDITIONING OF LIVER IN NON-HEART-BEATING DONORS BY AN ARTIFICIAL HEART AND LUNG MACHINE IN SITU", T. Endoh et al., <u>Transplantation Proceedings</u> , Vol. 28, No. 1, pgs. 110-115, Feb. 1996.					
		"MACHINE PERFUSION OF ISOLATED KIDNEY AT 37°C USING PYRIDOXALATED HEMOGLOBIN-POLYOXYETHYLENE (PHP) SOLUTION, UW SOLUTION AND ITS COMBINATION", T. Horiuchi et al., <u>Biomaterials, Art. Cells & Immob. Biotech.</u> , Vol. 20, Nos. 2-4,, pgs. 549-555, 1992.					
		"ANALYSIS OF THE OPTIMAL PERFUSION PRESSURE AND FLOW RATE OF THE RENAL VASCULAR RESISTANCE AND OXYGEN CONSUMPTION IN THE HYPOTHERMIC PERFUSED KIDNEY", R. Grundmann, M.D. et al., <u>Surgery</u> , Vol. 77, No. 3, pp. 451-461, March 1975.					
		"AN EXPERIMENTAL MODEL FOR ASSESSMENT OF RENAL RECOVERY FROM WARM ISCHEMIA", Paula Jablonski et al., <u>Transplantation</u> , Vol. 35, No. 3, pp. 198-204, March 1983.					
		"PRESERVATION OF THE ISOLATED KIDNEY UNDER NORMOTHERMIC CONDITIONS BY PERFUSION WITH PERFLUOROTRIBUTYLAMINE EMULSION", N.N. Kontuganov et al., Article published by Plenum Publishing Corporation, pp. 371-374, 1983.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. OWEN et al. FILING DATE July 11, 2003			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		3,881,990	05/06/75	BURTON et al.			
		3,712,583	1-1973	MARTINDALE et al.			
		5,051,352	9-1991	MARTINDALE et al.			
		3,845,974	11-1974	PELLOUX-GERVAIS			
		5,013,303	5-1991	TAMARI et al.			
		5,879,329	3-1999	GINSBURG			
		5,928,182	7-1999	KRAUS et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		WO 97/43899	11/27/97	WIPO			
		WO 97/45527	12/04/97	WIPO			
		WO 96/29865	10/03/96	WIPO			
		WO 94/06292	03/31/94	WIPO			
		WO 91/09520	07/11/91	WIPO			
		0 376 763 A2	07/04/90	Europe			
		WO 88/05261	07/28/88	WIPO			
		545,332	10-1922	France			
		WO 96/13288	5-1996	WIPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. OWEN et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		5,326,706	7/1994	Yland et al.			
		6,024,698	2/2000	Brasile			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		WO 86/00812	2/1986	WIPO			
		WO 91/14364	10/1991	WIPO			
		WO 97/45527	12/1997	WIPO			
		WO 97/46091	12/1997	WIPO			
		WO 99/15011	4/1999	WIPO			
		2 592 306	12/1985	France			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		B.G. Rijkmans et al., "Six-Day Canine Kidney Preservation, Hypothermic Perfusion Combined with Isolated Blood Perfusion," February 1984, pp. 130-134.					
		Jan Van Der Wijk et al., "Six-Day Kidney Preservation in a Canine Model, Influence of a One-to-Four-Hour Ex Vivo Perfusion Interval," May 1983, pp. 408-411.					
		M.R. Buhl et al, "The Postanoxic Regeneration of 5'-Adenine Nucleotides in Rabbit Kidney Tissue during In Vitro Perfusion," 1976, pp. 175-181.					
		Gauke Kootstra et al, "A New Device Towards Intermediate Term Kidney Preservation - An Experimental Study," 1980, pp. 86-89.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. OWEN et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		6,100,082	08/2000	Hassanein			
		6,046,046	04/2000	Hassanein			
		5,965,433	10/1999	Gardetto et al.			
		5,823,986	10/1998	Peterson			
		5,730,720	03/1998	Sites et al.			
		5,716,378	02/1998	Minten			
		5,622,429	04/1997	Heinze			
		4,462,215	07/1984	Kuraoka et al.			
		4,494,385	01/1985	Kuraoka et al.			
		5,356,771	10/1994	O'Dell			
		5,362,622	11/1994	O'Dell et al.			
		5,385,821	01/1995	O'Dell et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		WO 91/03934	04/1991	WIPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. OWEN et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		5,217,860	06/1993	Fahy et al.			
		5,472,876	12/1995	Fahy			
		5,586,438	12/1996	Fahy			
		5,723,282	03/1998	Fahy et al.			
		5,821,045	10/1998	Fahy et al.			
		5,856,081	01/1999	Fahy			
		4,951,482	08/1990	Gilbert			
		4,837,390	06/1989	Reneau			
		4,717,548	01/1988	Lee			
		4,473,637	09/1984	Guibert			
		4,471,629	09/1984	Toledo-Pereyra			
		4,242,883	01/1981	Toledo-Pereyra			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03	APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. OWEN et al.		
				FILING DATE July 11, 2003		GROUP
U.S. PATENT DOCUMENTS						
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS
		4,186,565	02/1980	Toledo-Pereyra		
		3,995,444	12/1976	Clark et al.		
		3,935,065	01/1976	Doerig		
		3,914,954	10/1975	Doerig		
		3,892,628	07/1975	Thorne et al.		
		3,881,990	05/1975	Burton et al.		
		3,877,843	04/1975	Fischel		
		3,843,455	10/1974	Bier		
		3,810,367	05/1974	Peterson		
		3,777,507	12/1973	Burton et al.		
		3,753,865	08/1973	Belzer et al.		
		3,738,914	06/1973	Thorne et al.		
FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)						
EXAMINER				DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.03		APPLICATION NO. Rule 53(b) Div. of Appln No. 09/645,525	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT(S) Donald R. OWEN et al.			
				FILING DATE July 11, 2003		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		3,660,241	05/1972	Michielsen			
		3,639,084	02/1972	Goldhaber			
		3,654,085	04/1972	Norr et al.			
		3,632,473	01/1972	Belzer et al.			
		3,545,221	12/1970	Swenson et al.			
		3,406,531	10/1968	Swenson et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
EXAMINER				DATE CONSIDERED			
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							